IN THE COURT OF COMMON PLEAS
LAKE COUNTY, OHIO

STATE OF OHIO	)	**CASE NO. 18CR000472**
	)	
Plaintiff	)	**JUDGE EUGENE A. LUCCI**
	)	
vs.	)	**ORDER DENYING MOTION TO SUPPRESS EVIDENCE**
	)	
COLLIN F. ENGLER	)	
	)	
Defendant	)	

The court conducted an in-court, on-the-record hearing with counsel for both parties, commencing on January 13, 2020[1], to consider the defendant's motion to suppress evidence/motion in limine, and the defendant's motion to suppress breath test/motion in limine, both filed on January 9, 2019. For the following reasons, the court finds that the motions ought to be denied.

This case has a long procedural history. It arose out of a motorcycle accident on or about April 21, 2018, in which the defendant was the driver and his passenger, Abbigayl Foreman, was killed. On October 16, 2018, the defendant was indicted on one count of Operating a Vehicle Under the Influence of Alcohol (M-1), pursuant to R.C. 4511.19(A)(1)(a), one count of Operating a Vehicle Under the Influence of Alcohol (M-1), pursuant to R.C. 4511.19(A)(1)(d), two counts of Aggravated Vehicular Homicide (F-2), pursuant to R.C. 2903.06(A)(1)(a), one count of Aggravated Vehicular Homicide (F-3), pursuant to R.C. 2903.06(A)(2), and three counts of Involuntary Manslaughter (F-3), pursuant to R.C. 2903.04(B).

A hearing on the defendant's two motions to suppress was originally set for February 8, 2019. On February 5, 2019, the defendant filed a motion to continue the hearing, stating that an expert he had retained needed more records relating to the Intoxilyzer 8000 machine used to test the defendant's breath sample. The state did not oppose the motion, and the suppression hearing was cancelled. The defendant filed a motion to compel discovery on February 26, 2019. In it, the defendant requested an order

[1] The court heard testimony all day on January 13, 2020 and for approximately four hours on January 28, 2020.

from the court compelling the State of Ohio Department of Health to turn over all COBRA data relating to the Intoxilyzer 8000 machine at issue. On March 11, 2019, the Department of Health filed a motion to partially quash a subpoena and to deny the motion to compel. A hearing on the issues raised in these motions was held on May 10, 2019. Subsequently, the court ordered the Department of Health to produce some of the items demanded by the defendant. The Department of Health provided that information to the court, which then gave the original disks containing it to the defendant's attorneys on July 3, 2019.

On September 25, 2019, the court held a bond review hearing at which it was informed by the defense that their expert died, and they had no idea what happened to the Department of Health's disks. On that basis, the court granted the defendant leave to identify and hire a new expert. After the time to do so had lapsed, the court held a case management conference at which the parties mutually agreed to conduct the instant suppression hearing on January 13, 2020 and to begin a trial on February 11, 2020.

In his motion to suppress evidence, the defendant moved the court to suppress evidence of the observations of the police officers at the scene of the accident, of objects taken from the defendant's vehicle, and of statements made by the defendant. That motion was withdrawn by the defendant's attorney on January 28, 2020, at the start of the second day of his suppression hearing. Therefore, it is moot.

However, the defendant stood by his motion to suppress breath test, in which he argued that Intoxilyzer 8000 machines in general are not scientifically reliable and produce inaccurate, inconsistent results. He further claimed that there was a substantial lack of compliance with the regulations governing the use of the machine used to test him, and that it had not been in proper working order since 2012.[2]

Preliminarily, the court notes that Intoxilyzer 8000 machines are approved for use as evidential breath testing equipment, pursuant to O.A.C. 3701-53-02(A). Therefore, as long as results from them are analyzed in accordance with the guidelines established by the director of the Ohio Department of Health, defendants may not attack their general scientific reliability. *Cincinnati v. Ilg,* 141 Ohio St.3d 22, 2014-Ohio-4258, 21 N.E.3d 22,

[2] Motion, p. 16.

¶23. However, that does not prevent defendants from challenging the accuracy of specific test results. *Id.*, ¶ 24.

Strict compliance with Ohio Department of Health regulations is not required for test results to be admissible in court. *State v. Taylor,* 135 Ohio App.3d 634, 638, 735 N.E.2d 61 (6th Dist. 1999). *State v. Brown*, 109 Ohio App.3d 629, 672 N.E.2d 1050 (4th Dist. 1996). Instead, if issues of reliability are raised, "the state must introduce evidence of substantial compliance with the methods and procedures set forth in Ohio Adm. Code 3701-53-04(A)(1). The burden then shifts to the defendant to show that he or she was prejudiced by anything less than complete technical compliance with the relevant regulation(s)." *Id.*

Here, over the course of the two-day hearing, the state presented four witnesses, including three employees of the Ohio Department of Health and the police officer who administered the defendant's blood/alcohol test. The evidence adduced shows that, contrary to the defendant's claims, the Intoxilyzer 8000 machine used to test the defendant was properly calibrated, maintained, and in working order on the day of the accident at issue. It was properly certified as required pursuant to the Ohio Administrative Code, and fully operational. The officer who administered the breath test was properly trained in the machine's use, and substantially complied with the rules and regulations regarding such testing. See *State v. Burnside,* 100 Ohio St.3d 152, 2003-Ohio-5372, 797 N.E.2d 71.

In addition to these general findings, the court finds that the following specific arguments raised by the defendant lack merit.

CLAIM: THE INTOXILYZER 8000 WAS MARKED TO BE REPLACED

Gregory Marquis, an infrastructure specialist for the Ohio Department of Health, testified that an instrument "issues" log existed on the Intoxilyzer 8000 machine used to test the defendant.[3] After running tests on the machine on February 8, 2018, he put a note in the log saying "replace machine."[4] The defendant claimed that meant there was an issue with that machine, and that if the field technician charged with checking it had

[3] FTR, 1/13/2020, 4:01, 4:15.
[4] FTR, 1/13/2020, 4:15, 4:26.

seen the log he would not have recertified it.[5] Instead, the machine remained in use through the defendant's test.[6]

The court does not agree with that assertion. Marquis testified that his notation in the issues log did not necessarily imply there was a problem with the machine.[7] Instead, it meant that he had some kind of contact with or about it, probably either for trouble shooting or for routine maintenance.[8] In this instance, results of tests Marquis ran on the machine on February 8, 2018 were at the outer limits of, but still within, its tolerances. He explained that the notation meant that although the machine was still in working order, it should be on a watch list and replaced *if* it tested out of tolerance at some later date.[9] The court finds that testimony was credible. Therefore, the defendant's assertions on this point are without merit.

CLAIM: RECORDS WERE NOT MAINTAINED

The defendant noted that the results of calibration checks and records of calibration, maintenance, and repairs on Intoxilyzers must be maintained for three years, pursuant to O.A.C. 3701-53-04. See *State v. Lipsky,* 1st Dist. No. C-010473, 2002 WL 397748. Failure to substantially comply with this requirement has been found to be grounds to suppress the results. *Id.* However, there was either no, or only minimal, compliance with O.A.C. requirements in such cases. Here, testimony showed that the machine used to test the defendant was checked on March 21, 2018 by Craig Yanni, a Department of Health inspector. Mr. Yanni checked the machine for radio frequency interference, and the machine tested within normal limits. The reason for that recheck was not documented.[10] However, that appears to be the only record potentially missing regarding this machine, and "courts have been willing to find substantial compliance where there is some evidence of recordkeeping." *Id.* Based on this, the court finds substantial compliance here.

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[5] FTR, 1/27/2020, 12:45
[6] FTR, 1/27/2020, 12:45.
[7] FTR, 1/13/2020, 4:15.
[8] FTR, 1/13/2020, 4:15.
[9] FTR, 1/13/2020, 4:24.
[10] FTR, 1/27/2020, 10:15.

CLAIM: THE MANUAL PROMPTS WERE USED, RATHER THAN THE INSTRUMENT'S

The defendant said that the police officer improperly tested him. Specifically, he claimed that pursuant to O.A.C. 3701-53-02(E), breath samples must be analyzed according to the instrument display for the instrument being used. He said the officer administering the test followed prompts shown in the machine's manual instead. The court finds that the testimony on this question was, at best, inconclusive. For instance, the officer testified that the machine went through its functions and sequences according to the way he was trained to use it.[11] He was subsequently asked if he followed the prompts on the machine when he conducted tests, and he answered "yes."[12] Further, the machine told him what to do with the mouthpiece.[13] A follow-up question regarding the mouthpiece was, "So, did you follow the manual when it said do not replace the mouthpiece, or did you follow the prompts on the screen that said replace the mouthpiece?" After requesting clarification, the officer said he believed he put a new mouthpiece on.[14] But shortly thereafter, he said he usually does what the manual says.[15] And after that, he said he would need to see the video to tell for sure.[16]

Based on the above, the court cannot find that the officer improperly conducted the defendant's test. His testimony simply does not conclusively establish whether he followed the instrument prompts or the manual prompts. Furthermore, regardless of which prompts he followed, this seems like an exceedingly narrow, technical objection for which the defendant established no prejudice. As such, the court finds that the officer substantially complied with O.A.C. testing requirements.

CLAIM: THE OFFICER GAVE AN IMPROPER IMPLIED CONSENT ADVISEMENT

Sgt. Kenneth Roberts Jr. read the top paragraph of the reverse side of the Form 2255, the implied consent advisement, verbatim. He also summarized the period of a potential suspension as a consequence of refusing to be tested, as set forth on the bottom part of the Form 2255, "off the cuff." The defense contends that the officer either needed

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[11] FTR, 1/27/2020, 11:48.
[12] FTR, 1/27/2020, 12:05:50.
[13] FTR, 1/27/2020, 12:05:50.
[14] FTR, 1/27/2020, 12:08:25.
[15] FTR, 1/27/2020, 12:08:50.
[16] FTR, 1/27/2020, 12:09.

to be legally accurate as to the potential consequences of a suspension, or not mention it at all.

Under R.C. 4511.191(C)(1), any person arrested "for operating a vehicle while under the influence of alcohol" shall be advised, pursuant to R.C. 4511.191(E) and (F), of the consequences of his refusal to submit upon request to a chemical test and of the consequences of his submission to the test "if he is found to have a prohibited concentration of alcohol in the blood, breath, or urine." *City of Bryan v. Hudson*, 77 Ohio St.3d 376, 378, 674 N.E.2d 678, 679 (1997).

The court of appeals observed that to allow such an interpretation as proposed by the defendant in this case would be "to impose a requirement upon police officers that is so wholly impractical that it could not reasonably have been intended by the legislature in its drafting of the statute." The Ohio Supreme Court stated, in analyzing the construction of R.C. 4511.191, that it believes that the interpretation urged by the defendant in this case is not what the legislature intended. *City of Bryan v. Hudson*, at 379.

The officer's advisement conformed to the requirement of the statute, and this objection has no merit.

CLAIM: THE DRY GAS STANDARD WAS NOT TRACEABLE TO NIST

Substantial compliance with the administrative rules is required for admissibility of test results for breath-alcohol content. Once the state has shown substantial compliance with administrative rules for admissibility of test results of breath-alcohol content, the burden shifts to the defendant to demonstrate that he would be prejudiced by anything less than technical compliance. *State v. Taylor*; *State v. Brown*.

In order to comply with the state department of health alcohol-testing procedures set forth in the Ohio Administrative Code, both the general requirements of the code and more specific testing procedures set forth in appendices thereto must be followed to ensure the accuracy of the testing machine. If the state were permitted to follow only the requirements of the code and to ignore specific procedures set forth in the appendices, the goal of statewide uniformity in the testing accuracy of breath-testing equipment used to measure the level of alcohol in a person's blood would be frustrated. *State v. Kauffman* (Ohio App. 12 Dist., 10-16-1995) 106 Ohio App.3d 831, 667 N.E.2d 443.

Ohio Adm. Code 3701-53-04(B) provides:

> Instruments listed under paragraph (A)(3) of rule 3701-53-02 of the Administrative Code shall automatically perform a dry gas control using a dry gas standard traceable to the national institute of standards and technology (NIST) before and after every subject test.

The state demonstrated that the Intoxilyzer 8000 machine in use in this case automatically performed a dry gas control before and after each subject test, including the defendant's. The issue raised by the defense is whether the state used a dry gas standard traceable to the national institute of standards and technology (NIST).

The court must determine whether the state substantially complied with this regulation. If the court so finds, the court must then determine whether the defense has demonstrated that he would be prejudiced by anything less than technical compliance.

The certificate of analysis[17] provided to Guth Laboratories Inc. by CALGAZ, a division of Airgas USA LLC, declared the analytical accuracy of the DRYGAZ dry gas standard, ethanol in nitrogen, to be +/- 0.002 BrAC or +/- 2%, whichever is greater. The certificate identified the CALGAZ lot number of the standard, gave the date of manufacture as July 6, 2017, and its expiration date as July 6, 2020. It stated that the reference standard was cylinder ND50144, gave the cylinder size, and stated it had a concentration of 261.1 ppm using National Metrology Institute (NMI) traceable standards.

As to traceability, specifically, the certificate states that, in its preparation, the gas mixtures were manufactured with balances calibrated by an ISO 17025 accredited company using NIST traceable weights and meets or exceeds the requirements of NIST Handbook 44. It further provides the calibration test protocols. The certificate also states that the analytical instruments were calibrated using NMI traceable standards[18], and it provided those certification numbers. The certificate of analysis stated that there were no affecting environmental conditions present during the analysis.

The certificate added, in a sort of footnote, that:

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[17] State's Exhibit 8.

[18] This is the only portion of the certificate of analysis where the defense claims the state did not comply with the technical requirements of the code. The defense contends that since "NMI" is written, and not "NIST," this is evidence of non-compliance with the administrative code. The defense cited the court to a recent Licking County Common Pleas Court decision ruling that the use of "NMI" traceable standards instead of "NIST" traceable standards renders the testing invalid and inadmissible. I disagree.

NMI is recognized by NIST through the Mutual Recognition Agreement (CIPM MRA). CALGAZ calibration devices were found to meet all applicable requirements of the National Highway Traffic Safety Administration Model Specifications for calibrating units for breath alcohol testers.

"We certify that all the cylinders for the Lot numbers identified herein are manufactured and tested within the requirements of CFR 49 Part 178.65 and that physical and chemical test reports are on file and copies will be furnished upon request."

The certificate of analysis states specifically that the dry gas mixture was manufactured with balances calibrated by an ISO 17025 accredited company using NIST traceable weights. The issue then becomes whether any analytical instruments used in the process, possibly including an infrared spectrometer, which were calibrated using NMI traceable standards, substantially complies with the code.

The court has no evidence of what, if any, analytical instruments were used prior to Guth Laboratories Inc. certifying the analysis of the dry gas standard provided for use by the Ohio department of health in this Intoxilyzer 8000 machine. Assuming that there were analytical instruments used, then those instruments, according to the certificate, were calibrated using NMI traceable standards. Does the certificate need to say that the analytical instruments were calibrated "using NIST traceable standards" to be admissible according to the code? The entire discussion that follows is intended to show that it need not state specifically that NIST standards, rather than NMI standards, were employed in the analytical instrument calibrations, especially where the gas mixture itself states that it was manufactured using a dry gas standard traceable to NIST.

The National Institute of Standards and Technology (NIST) is an agency of the Department of Commerce. Its role as the National Metrology Institute (NMI) for the United States was established by Congress in 1901. As such, NIST has the responsibility "to develop, maintain and retain custody of the national standards of measurement, and to provide the means and methods for making measurements consistent with those standards; to assure the compatibility of United States national measurement standards with those standards; and *to assure the compatibility of United States national*

measurement standards with those of other nations."[19] (Emphasis added.) The job of NIST is twofold: to ensure U.S. national standards are accurate realizations of the SI[20] units and to transfer the values of those standards to the U.S. measurement system through calibrations and other types of measurement services.[21]

NIST states that the definition of traceability that has achieved global acceptance in the metrology community is the one contained in the International vocabulary of metrology (VIM[22]) - Basic and general concepts and associated terms [1]: "...property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

It is important to note that traceability is the property of the result of a measurement, not of an instrument or calibration report or laboratory. It is not achieved by following any one particular procedure or using special equipment. Merely having an instrument calibrated, even by NIST, is not enough to make the measurement result obtained from that instrument traceable to realizations of the appropriate SI unit or other specified references. The measurement system by which values and uncertainties are transferred must be clearly understood and under control.[23]

NIST states that organizations cannot be traceable. Only measurement results can be traceable.[24]

According to the internationally recognized VIM definition, metrological traceability is a property of a measurement result by which that result is related to specified reference standards, not to institutions. *Accordingly, the phrase "traceable to NIST", in its most proper sense, is shorthand for "metrologically traceable to NIST's practical realization of the definition of a measurement unit".*[25] (Emphasis added.)

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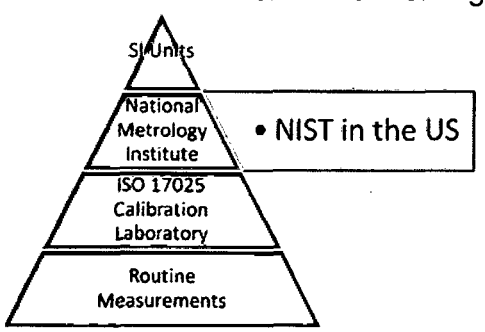
[19] 15 U.S.C. 271.
[20] The International System of Units, SI, discussed *infra*.
[21] See http://www.nist.gov/. Supplementary Materials related to NIST Policy on Metrological Traceability, nist.gov/traceability/supplementary-materials-related-nist-policy-metrological-traceability. FAQ I.C.1 What is NIST?
[22] International Vocabulary of Metrology (VIM) is discussed, *infra*.
[23] Supplementary Materials related to NIST Policy on Metrological Traceability https://www.nist.gov/traceability/supplementary-materials-related-nist-policy-metrological-traceability#certificates. FAQ I.A.1 What is traceability?
[24] *Id.* FAQ I.A.3 Is it correct to say that an organization is traceable?
[25] *Id.* FAQ I.C.3 What is meant by the phrase "traceable to NIST"?

In general, NIST establishes the traceability of its own measurement results by following the prescription of the VIM definition of traceability, that is, through an unbroken chain of calibrations, including determining the uncertainties at each step, to specified references. In the case of the SI units, for six of the seven base units the ultimate stated reference is a CIPM-established[26] definition of the units, including associated procedures; for one SI unit, mass, the reference is specified as the international prototype kilogram.[27]

NIST only certifies the traceability of measurement results that NIST itself provides, either directly or through an official NIST program or collaboration. NIST cannot be responsible for claims of traceability made by others since the process of demonstrating traceability requires that most of the steps be taken at the site of whoever is claiming traceability. NIST has no control over this process and no direct involvement in the day-to-day activities at the site.[28]

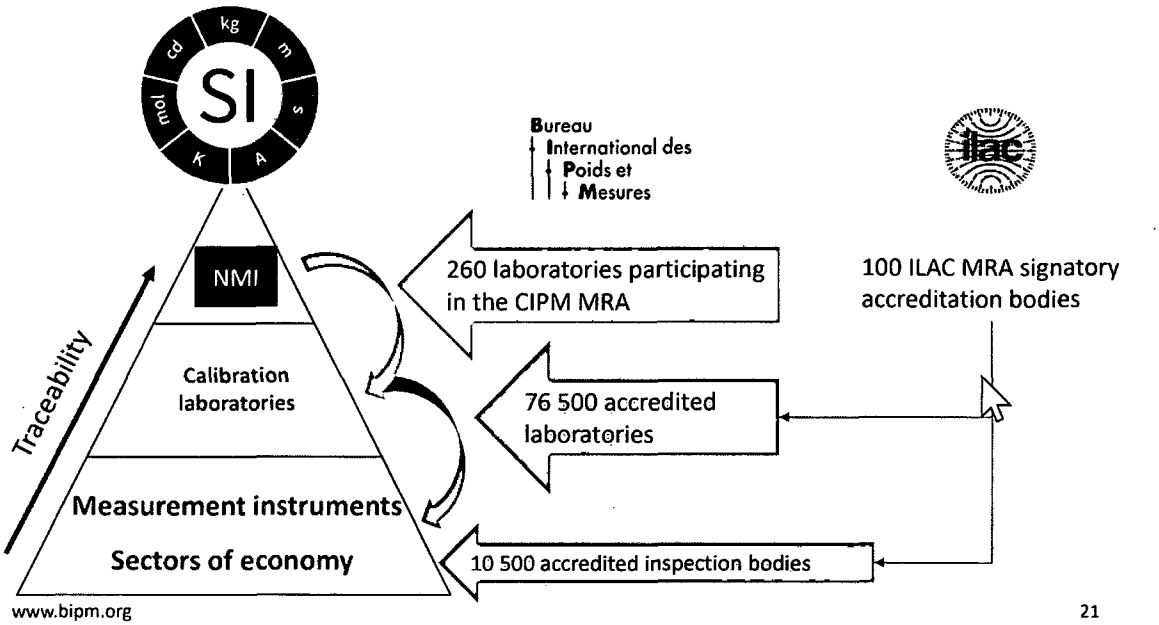
Further, merely having an instrument or artifact calibrated at NIST is not enough to make the measurement result traceable to reference standards developed and maintained by NIST.[29]

Because it is not affordable, efficient, or even possible for everybody within a country to work directly with their NMI, *NMI-level calibration standards* are used to calibrate primary calibration standards or instruments; primary standards are then used to calibrate secondary standards; secondary standards are used to calibrate working standards; and working standards are used to calibrate process instruments. In this way, references to the SI standards can be efficiently and affordably passed down the calibration pyramid through the NMI, into industry as needed. To state this graphically and put it into perspective, when the code states that a dry gas standard must be traceable to NIST, it means that it must be



[26] International Conference on Weights and Measures (CIPM), discussed *infra*.
[27] Supplementary Materials related to NIST Policy on Metrological Traceability https://www.nist.gov/traceability/supplementary-materials-related-nist-policy-metrological-traceability#certificates. FAQ I.C.5 How does NIST establish the traceability of its own measurement results?
[28] *Id.* FAQ I.C.8 Does NIST certify the traceability of measurement results other than its own?
[29] *Id.* FAQ I.D.3 If I have an instrument or artifact calibrated at NIST, does that make my measurement results traceable to those of NIST?

an NMI-level calibration traceable to a practical realization of the definition of a measurement SI unit.



To establish traceability to such reference standards, there must be an unbroken chain of calibrations and each provided measurement must be accompanied by a statement of uncertainty. The measurement system by which values are transferred must be clearly understood and under control. The dates and details of each link in the chain must also be provided. In this case, a statement of uncertainty, the measurement system, and the dates and details thereof were provided by the supplier of the dry gas standard.

Under certain circumstances, customers can claim traceability to NIST for measurement results associated with something that NIST cannot calibrate directly, if well-accepted, scientifically sound and appropriate measurement equipment, practices, and procedures are used; if measurement values and uncertainties are calculated or otherwise established according to well-established protocols; and if the uncertainties are within accepted norms (both low and high) for the measurement application; then the customer's measurement result might be considered traceable to NIST.[30]

[30] *Id.* FAQ I.D.9 Can customers claim traceability to NIST for measurement results associated with something that NIST cannot calibrate directly?

Accordingly, traceability to NIST cannot mean that NIST actually prepared and analyzed the gas mixture; it does mean that well-accepted, scientifically sound and appropriate equipment, practices, and procedures must be used, including a calculation of uncertainties. How do we know that an NMI, such as that of another country, for instance, Britain, Australia, Thailand, or Malaysia, uses standards that are metrologically traceable to NIST's practical realization of the definition of a measurement unit? In other words, are the measurement units related to the SI unit?

The Metre Convention (Convention du Mètre) is the treaty that created, in 1875, the Bureau International des Poids et Mesures (International Bureau of Weights and Measures or BIPM), which is the intergovernmental organization through which member states act together on matters related to measurement science and measurement standards.[31] The United States provided the impetus and was at the forefront of the treaty, which has force as the supreme law of the land in the U.S., pursuant to the U.S. Constitution. 20 Stat. 709; Treaty Series 378; U.S. Const., Section Article VI, cl. 2.[32] The United States ratified the convention, is a state party to the convention, and is a member state of the BIPM.

Among its objectives, the BIPM is to be the coordinator of the world-wide measurement system, ensuring it gives comparable and internationally accepted measurement results. In so doing, it coordinates activities between the National Metrology Institutes (NMIs) of member states and the Regional Metrology Organizations (RMOs), including the provision of technical services to support the CGPM Conference General des Poids et Mesures (International Conference on Weights and Measures or CIPM) Mutual Recognition Arrangement (MRA) and the infrastructure for the development and promotion of the International System of Units (SI).[33]

International trade is hampered by one country not recognizing the quality controls in place in other countries – often due to standards being different or being incompatible with each other. At the 20th CGPM (1995), it was recognized that although ad-hoc

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[31] https://www.bipm.org/en/worldwide-metrology/metre-convention/.

[32] "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Constitution, Section Article VI, cl. 2.

[33] https://www.bipm.org/en/about-us/role.html.

recognition of instrument calibration between cooperating countries had been taking place for a hundred years, a need had arisen for a more comprehensive agreement. Consequently, the CIPM was mandated to investigate the setting up of a Mutual Recognition Agreement in respect of instrument calibration. Any such agreement would require the keeping of records that could demonstrate the traceability of calibrations back to the base standards. Such records would be recorded within an ISO 9000 framework. Four years later, in 1999 the text of the CIPM-MRA was agreed at the 21st CGPM.[34]

The CIPM MRA is the framework through which NMIs demonstrate the international equivalence of their measurement standards and the calibration and measurement certificates they issue. The outcomes of the arrangement are the internationally recognized (peer-reviewed and approved) Calibration and Measurement Capabilities (CMCs) of the participating institutes. Approved CMCs and supporting technical data are publicly available from the CIPM MRA database (the KCDB).[35]

The CIPM MRA has been signed by the representatives of 106 institutes – from 62 member states, 40 associates of the CGPM, and 4 international organizations – and covers a further 157 institutes designated by the signatory bodies.[36] The U.S. is a member state. The National Institute of Standards and Technology (NIST) is the NMI of the U.S., and has been participating in the CIPM MRA since October 14, 1999.[37]

RMOs are regional associations of national metrology institutes. They have a wide range of activities, as described on their websites. The RMOs have a role within the framework of the CIPM MRA. Currently six RMOs are recognized within the framework of the CIPM MRA. The U.S. is a member of the Sistema Interamericano de Metrologia or Inter-American Metrology System (SIM).

In the fulfillment of the CIPM MRA, an NMI is required to have its quality management system reviewed and approved by its Regional Metrology Organization (RMO). SIM representation includes the 34 member countries of the Organization of American States (OAS). SIM is responsible for reviewing the quality management systems submitted by its member NMIs and reporting on their acceptance or rejection.

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[34] https://www.bipm.org/en/cipm-mra/historical.html; https://www.bipm.org/en/cipm-mra/cipm-mra-text/.
[35] https://www.bipm.org/en/cipm-mra/.
[36] https://www.bipm.org/en/cipm-mra/.
[37] https://www.bipm.org/en/cipm-mra/participation/signatories.html.

SIM reports to the Joint Committee of the Regional Metrology Organizations and the BIPM (JCRB), which in turn uses this process to help build confidence among the NMIs by establishing a transparent quality management system (QMS) review process, which is mutually acceptable among all RMOs.

It stands to reason that if the SIM, CIPM MRA, and BIPM did not engage in scientific measurement based traceability to SI base units, then NIST justifiably would not be a founder, signatory, and member.

The BIPM has established the base units in seven realms of measurement: time (the second), length (the meter), mass (the kilogram), electric current (the ampere), thermodynamic temperature (the kelvin), luminous intensity (the candela), and the amount of substance (the mole). The organization sets the denomination of prefixes (e.g. "mega"), its exponential factor (e.g. 10^6), symbol (e.g. "M"), and multiplying factor (e.g. 1,000,000). This is the International System of Units (Système international d'unités or SI), the system most widely used around the world, and the one used by NIST. NIST expresses breath alcohol content measurement results using the SI established by the BIPM, namely in terms of grams per liter.[38]

The Mutual Recognition Arrangement (MRA) has been drawn up by the CIPM, under the authority given to it in the Metre Convention, for signature by directors of the NMIs of member states of the Convention.

A key objective of the MRA is to foster confidence in measurements. Confidence in measurements is an essential prerequisite to international trade and facilitates almost every task in the industrialized world. To a large extent this confidence already exists and is based on the SI, which is the cornerstone of the international measurement system, as realized by the NMIs. The function of this mutual recognition arrangement is to extend and consolidate pre-existing worldwide confidence in measurements.[39]

NMI directors sign the MRA with the approval of the appropriate authorities in their own country and thereby: (1) accept the process specified in the MRA for establishing the database; (2) recognize the results of key and supplementary comparisons as stated in

[38] https://www.bipm.org/en/measurement-units/.
[39] Mutual Recognition of National Measurement Standards and of Calibration and Measurement Certificates Issued by National Metrology Institutes, CIPM MRA, Par. 7.1.

the database; and (3) *recognize the calibration and measurement capabilities of other participating NMIs as stated in the database.*[40] (Emphasis added.)

Accordingly, NIST, as a signatory to the CIPM MRA, agrees to recognize the national measurement standards and calibration and measurement certificates issued by NMIs who have also signed on and are member states. This arrangement provides for the mutual recognition of national measurement standards and of calibration and measurement certificates issued by national metrology institutes, and is founded on the efforts of each individual national metrology institute to base its measurements and measurement uncertainties on SI units.[41]

To put the criteria for mutual recognition on an objective footing, the arrangement calls upon: (a) the results of a set of key comparisons carried out using specified procedures which lead to a quantitative measure of the degree of equivalence of national measurement standards; (b) the operation by each NMI of a suitable way of assuring quality; and (c) successful participation by each NMI in appropriate supplementary comparisons. Together, these three procedures demonstrate to participating institutions the degree to which each may have confidence in the results reported by others, and so promote mutual confidence between them.[42]

For the purposes of this arrangement, the degree of equivalence of measurement standards is taken to mean the degree to which these standards are consistent with reference values determined from the key comparisons and hence are consistent with one another. Each reference value is referred to as a key comparison reference value and, in most cases, it can be considered to be a close, but not necessarily the best, approximation to the SI value. The degree of equivalence of a national measurement standard is expressed quantitatively in terms of its deviation from the key comparison reference value and the uncertainty of this deviation.[43]

This arrangement is in two parts: through part one, signatories recognize the degree of equivalence of national measurement standards of participating national

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[40] *Id.* CIPM MRA, Engagement.
[41] https://www.bipm.org/en/cipm-mra/cipm-mra-text/section1.html.
[42] CIPM MRA, Preamble.
[43] *Id.*

metrology institutes; through part two, the signatories recognize the validity of calibration and measurement certificates issued by participating institutes.[44]

As the National Metrology Institute (NMI) for the United States, the National Institute of Standards and Technology (NIST), formerly the National Bureau of Standards, has provided measurement services, both calibrations and reference materials, for more than 100 years.[45]

In response to the signing of the International Committee for Weights and Measures (CIPM) Mutual Recognition Arrangement (MRA), NIST first established an institution-wide quality system for the measurement services 10 years ago.[46] NIST's Quality System for Measurement Services has advanced the quality of service and measurements it provides its customers by fostering an environment in which NIST management and staff work towards continual improvement in the development and delivery of NIST measurement services.[47]

"The CIPM MRA is a driver for the NIST quality system." The emergence of a more globalized economy necessitated a comprehensive scheme to provide confidence for the equivalence of national measurement services, which ensure the technical basis for international trade, commerce and regulatory matters. The International Committee of Weight and Measures (CIPM) responded by implementing a "Mutual Recognition Arrangement of national measurement standards and of calibration and measurement certificates issued by national metrology institutes" (CIPM MRA). The CIPM MRA was first signed in October of 1999 by the directors of the national metrology institutes (NMIs) from 38 Member States of the Metre Convention (NIST being one of the 38) and representatives from 2 international organizations.[48]

The CIPM MRA calls for signatories/NMIs to participate in international comparisons of measurements (known as key comparisons) and supplementary

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[44] *Id.*

[45] The NIST Quality System for Measurement Services: A Look at its Past Decade and a Gaze towards its Future, Sally Bruce, National Institute of Standards and Technology, https://tsapps.nist.gov/publication/get_pdf.cfm?pub_id=913859.

[46] http://www.bipm.org/en/cipmmra/objectives.html.

[47] *Id.*

[48] "The NIST Quality System for Measurement Services: A Look at its Past Decade, and a Gaze towards its Future," Sally Bruce, National Institute of Standards and Technology, https://tsapps.nist.gov/publication/get_pdf.cfm?pub_id=913859.

international comparisons of measurements; implement quality systems; and demonstrate competence. Those original signatories had a 5-year deadline to implement their quality system and demonstrate its use in support of their measurement capabilities. Typically, in that five-year implementation period, the NMIs were also submitting their Calibration and Measurement Capabilities (CMCs), which are found in Appendix C of the CIPM MRA. The CMCs are the quantities for which calibration and measurement certificates are recognized by the institutes participating in the MRA.[49]

Prior to the implementation of the formal NIST quality system, informal quality practices, policies, and procedures existed. In some parts of the organization, quality systems had been adopted that followed International Organization for Standardization (ISO) guide (25) and the American National Standards Institute (ANSI) standard (Z540-1) for calibration laboratories.[50]

Nevertheless, the NIST-wide quality system, initiated in 2003, represented a significant step towards providing its customers and international peers with overall confidence in the quality of NIST's measurements institution-wide. Internally, it benefitted NIST by creating an environment for management and staff to work towards continual improvement in the development and delivery of NIST measurement services.[51]

NIST's policy for measurement traceability is significant for NMIs. It is NIST policy to establish traceability of the results of its own measurements and values of its own standards and of results and values provided to customers of NIST measurement services. Consistent with the CIPM, NIST measurements are directly traceable to the SI (or for chemical or materials metrology to other recognized standards) as realized or represented by NIST. For measurements that do not provide a significant influence on the overall measurement uncertainty, e.g., ambient temperature, traceability can also be

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[49] The NIST Quality System for Measurement Services: A Look at its Past Decade and a Gaze towards its Future, Sally Bruce, National Institute of Standards and Technology, page 2, https://tsapps.nist.gov/publication/get_pdf.cfm?pub_id=913859.

[50] *Id.*

[51] *Id.*

obtained from a calibration laboratory that is accredited by an ILAC-signatory[52] accreditation body.[53]

The International Bureau of Weights and Measures (BIPM), the International Organization of Legal Metrology (OIML),[54] the International Laboratory Accreditation Cooperation (ILAC)[55] and the International Organization for Standardization (ISO)[56] are four international bodies responsible for metrology, accreditation and standardization worldwide.[57] All four bodies collaborate, with other international stakeholders, in the Joint Committee for Guides in Metrology (JCGM) responsible for developing common documents. Two JCGM documents key to this Declaration are a guide to expression of uncertainty in a variety of metrological situations and the International Vocabulary of Metrology (VIM).[58]

In particular, the VIM defines metrological traceability as: "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty". This is the definition used by NIST. Metrological traceability therefore

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[52] International Laboratory Accreditation Cooperation (ILAC).

[53] The NIST Quality System for Measurement Services: A Look at its Past Decade and a Gaze towards its Future, Sally Bruce, National Institute of Standards and Technology, page 4, https://tsapps.nist.gov/publication/get_pdf.cfm?pub_id=913859.

[54] The International Organisation of Legal Metrology (OIML) promotes the global harmonization of legal metrology laws and procedures and provides its members with guidance with respect to their national legislation, including that measurements used for trade and regulatory purposes should be made using standards legally traceable to the SI.

[55] The International Laboratory Accreditation Cooperation (ILAC) is the global association for the accreditation of laboratories, inspection bodies, proficiency testing providers and reference material producers, with a membership consisting of accreditation bodies and stakeholder organisations throughout the world.

[56] The International Organization for Standardization (ISO), ISO is an independent, nongovernmental international organization with a membership of national standards bodies. Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges. ISO publishes a range of standards that apply to manufacture and testing of various products, and the provision of services. In many cases, calibration and testing form an integral part of the requirements of the standards. ISO harmonizes its terminology with the VIM and frequently incorporates measurement-related clauses in these standards. NIST, the NMI for the U.S., has a mature quality system based on ISO. Note that ISO is not an acronym; instead, the name derives from the Greek word "iso," which means equal. Founded in 1946, ISO is an international organization composed of national standards bodies from over 75 countries. For example, ANSI (American National Standards Institute) is a member of ISO.

[57] https://www.bipm.org/en/worldwide-metrology/bipm-oiml-ilac-iso_joint_declaration.html.

[58] https://www.bipm.org/utils/common/pdf/BIPM-OIML-ILAC-ISO_joint_declaration_2018.pdf.

embodies the concepts of measurement uncertainty and calibrations against a hierarchy of reference standards.[59]

The Joint BIPM, OIML, ILAC, and ISO Declaration on Metrological Traceability, originally signed on November 9, 2011, and updated and reaffirmed on November 13, 2018, expresses the statement by those four organizations and their constituent members that there is a worldwide measurement system which provides a robust, internationally accepted framework within which users can have confidence in the validity and acceptability of measurement results, and that legislators and regulators should refer to the CIPM Mutual Recognition Arrangement, the ILAC Mutual Recognition Arrangement, and the OIML Certification System and accept measurement results made within them, thereby helping avoid technical barriers to trade.[60]

Metrological traceability is one of the elements that establishes international confidence in the worldwide equivalence of measurements. The framework described in this document enables legislators, regulators and exporters/importers to take advantage of an international set of mutually supportive systems, which demonstrate equivalence of measurements, thereby significantly reducing technical barriers to trade (TBTs), which might otherwise result from a lack of equivalence.[61]

The National Metrology Institutes (NMIs) are tasked with the realization, maintenance, improvement and dissemination of the SI units via traceable calibration and measurement services based on their Calibration and Measurement Capabilities (CMCs).[62]

The CIPM Mutual Recognition Arrangement (MRA) was drawn up by the International Committee of Weights and Measures (CIPM) under the authority given to it in the Metre Convention, for signature by directors of member National Metrology Institutes (NMIs).[63]

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[59] https://www.nist.gov/calibrations/traceability; https://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf, page 29-30, which includes eight notes in amplification of the definition.
[60] https://www.bipm.org/utils/common/pdf/BIPM-OIML-ILAC-ISO_joint_declaration_2018.pdf.
[61] *Id.*
[62] https://www.bipm.org/utils/common/pdf/BIPM-OIML-ILAC-ISO_joint_declaration_2011.pdf.
[63] https://www.bipm.org/en/cipm-mra/objectives.html.

The principal objectives of the MRA are to establish through measurement comparisons the degree of equivalence of national measurement standards maintained by NMIs, to provide for the mutual recognition of calibration and measurement certificates issued by NMIs, and to provide a secure technical foundation for wider agreements related to international trade, commerce, and regulatory affairs. The mutual recognition of calibration and measurement certificates requires that each NMI participate in the activities of the International Bureau of Weights and Measures (BIPM) (including key measurement comparisons) and have a suitable way of assuring quality in the results of its measurement services. The results of the key measurement comparisons and specific statements of the calibration and measurement capabilities (CMCs) of each signatory NMI are entered in an MRA database originally developed by NIST and now maintained by the Bureau of International Weights and Measures at http://kcdb.bipm.org/. While NIST recognizes the validity of the other signatories' certificates, such recognition does not mean that measurement results traceable to any other signatory are therefore traceable to NIST. The burden of establishing traceability of its measurement results to NIST, and of supporting an associated claim of traceability, is on the individual NMI providing the service.[64]

The court determines that the dry gas used by the Ohio Department of Health in this case was, in fact, metrologically traceable to NIST's practical realization of the definition of a measurement unit, and is therefore, traceable to NIST.

The court determines that an appropriate statement of traceability that complies with the technical requirements of the code would be: The company providing the dry gas standard certifies that the ethanol breath standard meets or exceeds published measurement specifications and has been calibrated using standards traceable to National Metrology Institutes (such as NIST) that are linked to the international system of units (SI). The policies and procedures used at the company providing the dry gas standard are based on ISO 9001/IEC 17025.

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[64] Supplementary Materials related to NIST Policy on Metrological Traceability https://www.nist.gov/traceability/supplementary-materials-related-nist-policy-metrological-traceability#certificates. FAQ I.E.1 What is the CIPM MRA and what does it have to do with traceability?

The court finds that the state substantially complied with this regulation set forth at Ohio Adm. Code 3701-53-04(B). The court further finds that the defendant has not demonstrated that he would be prejudiced by anything less than technical compliance.

The court, having found that the state substantially complied with all of the requirements of the code, the defense failing to demonstrate that he was prejudiced by less than technical compliance, the court overrules the motion to suppress evidence. Any other allegations of insufficient compliance with the administrative rules are also hereby overruled. The motion to suppress evidence is denied.

IT IS SO ORDERED.

EUGENE A. LUCCI, JUDGE

c: Rocco W. DiPierro, Esq. and Rachael E. Wood, Esq.
Assistant Prosecuting Attorneys
Joseph D. Hada, Esq., Attorney for Defendant
Richard J. Perez Esq., Attorney for Defendant

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